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File: USPT

Oct 20, 1998

US-PAT-NO: 5824341

DOCUMENT-IDENTIFIER: US 5824341 A

TITLE: Composition providing selective release of an active ingredient

DATE-ISSUED: October 20, 1998

## INVENTOR-INFORMATION:

NAME	CITY	STATE	ZIP CODE	COUNTRY
Seth; Pawan	Strasbourg			FR
Stamm; Andre	Griesheim			FR

US-CL-CURRENT: 424/473; 424/472, 424/489

## CLAIMS:

What is claimed is:

1. A composition comprising, successively:

(a) a core (1) consisting of a water-swellaable material;

(b) a layer (2) of an elastic material that allows water to pass and is insoluble in water;

(c) a layer (3) containing at least one active ingredient; and

(d) a layer (4) of a material that is water-permeable in a predetermined aqueous medium, wherein said layer (4) is capable of rupturing under the effect of expansion of said core (1).

2. The composition of claim 1, wherein said core (1) is capable of exhibiting a volume expansion of from about 50 to about 700%.

3. The composition of claim 1, wherein said core (1) is capable of exhibiting a volume expansion of from about 100 to about 500%.

4. The composition of claim 1, wherein said core (1)

weighs from about 30 to about 90% of the total weight of said composition, said elastic material of layer (2) weighs from about 1 to about 6% of the total weight of said composition, said layer (3) containing at least one active ingredient weighs from about 1 to about 60% of the total weight of said composition, and said material of layer (4) weighs from about 3 to about 15% of the total weight of said composition.

5. The composition of claim 1, wherein said core (1) weighs from about 50 to about 70% of the total weight of said composition, said elastic material of layer (2) weighs from about 2 to about 4% of the total weight of said composition, said layer (3) containing at least one active ingredient weighs from about 10 to about 50% of the total weight of said composition, and said material of layer (4) weighs from about 5 to about 9% of the total weight of said composition.

6. The composition of claim 1, wherein said material of layer (4) comprises a polymeric material that is soluble in said predetermined aqueous medium, wherein said predetermined aqueous medium has a pH of from about 6 to about 8.

7. The composition of claim 1, wherein said material of layer (4) comprises a polymer material that is soluble in said predetermined aqueous medium, wherein said predetermined aqueous medium has a pH of from about 6.8 to about 8.

8. The composition of claim 1, wherein said material of layer (4) is a gastro-resistant and entero-soluble material.

9. The composition of claim 1, wherein said layer (3) comprises from about 5 to about 100 mg of active ingredient.

10. A composition comprising, successively:

- (a) a core (1) consisting of a water-swellaable material;
- (b) a layer (2) of an elastic material that allows water to pass and is insoluble in water;

(c) a layer (3) comprising prednisolone or a pharmaceutically-acceptable derivative thereof; and

(d) a layer (4) of a material that is water-permeable in a predetermined aqueous medium, wherein said layer (4) is capable of rupturing under the effect of expansion of said core (1).

11. The composition of claim 10, wherein said core (1) is capable of exhibiting a volume expansion of from about 50 to about 700%.

12. The composition of claim 10, wherein said core (1) is capable of exhibiting a volume expansion of from about 100 to about 500%.

13. The composition of claim 10, wherein said core (1) weighs from about 30 to about 90% of the total weight of said composition, said elastic material of layer (2) weighs from about 1 to about 6% of the total weight of said composition, said layer (3) comprising prednisolone or a pharmaceutically-acceptable derivative thereof weighs from about 1 to about 60% of the total weight of said composition, and said material of layer (4) weighs from about 3 to about 15% of the total weight of said composition.

14. The composition of claim 10, wherein said core (1) weighs from about 50 to about 70% of the total weight of said composition, said elastic material of layer (2) weighs from about 2 to about 4% of the total weight of said composition, said layer (3) comprising prednisolone or a pharmaceutically-acceptable derivative thereof weighs from about 10 to about 50% of the total weight of said composition, and said material of layer (4) weighs from about 5 to about 9% of the total weight of said composition.

15. The composition of claim 10, wherein said material of layer (4) comprises a polymeric material that is soluble in said predetermined aqueous medium, wherein said predetermined aqueous medium has a pH of from about 6 to about 8.

16. The composition of claim 10, wherein said material of layer (4) comprises a polymer material that is soluble in

said predetermined aqueous medium, wherein said predetermined aqueous medium has a pH of from about 6.8 to about 8.

17. The composition of claim 10, wherein said material of layer (4) is a gastro-resistant and entero-soluble material.

18. The composition of claim 10; wherein said layer (3) comprises from about 5 to about 100 mg of prednisolone or a pharmaceutically-acceptable derivative thereof.

19. A composition comprising, successively:

(a) a core (1) consisting of a water-swellaable material, said core weighing from about 30 to about 90% of the total weight of said composition, and said core is capable of exhibiting a volume expansion of from about 100 to about 500%;

(b) a layer (2) of a water permeable elastic material that is insoluble in water, said layer (2) weighing from about 1 to about 6% of the total weight of said composition;

(c) a layer (3) comprising prednisolone or a pharmaceutically-acceptable derivative thereof, said layer (3) weighing from about 1 to about 60% of the total weight of said composition; and

(d) a layer (4) of a material that is water-permeable in a predetermined aqueous medium, said layer (4) weighing from about 3 to about 15% of the total weight of said composition, wherein said layer (4) is capable of rupturing under the effect of expansion of said core (1), and wherein said material of layer (4) is soluble in said predetermined aqueous medium, wherein said predetermined aqueous medium has a pH of from about 6 to about 8.

20. A method for treating diseases of the colon comprising the step of administering a composition according to claim 1.

21. A method for treating diseases of the colon comprising the step of administering a composition according to claim 19.

22. A method for treating diseases of the colon comprising the step of administering a composition according to claim 19.

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NAME	CITY	STATE	ZIP CODE	COUNTRY
Seth; Pawan	Strasbourg			FR
Stamm; Andre	Griesheim			FR

## ASSIGNEE-INFORMATION:

NAME	CITY	STATE	ZIP CODE	COUNTRY	TYPE CODE
Pharma Pass				FR	03

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DATE FILED: April 22, 1997

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## PCT-DATA:

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PCT/FR95/01079	August 11, 1995	WO96/04893	Feb 22, 1996	Apr 22, 1997	Apr 22, 1997

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US-CL-CURRENT: 424/473; 424/472, 424/489

FIELD-OF-SEARCH: 424/489, 424/473, 424/472, 424/449

PRIOR-ART-DISCLOSED:

U.S. PATENT DOCUMENTS

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	PAT-NO	ISSUE-DATE	PATENTEE-NAME	US-CL
<input type="checkbox"/>	<u>4968208</u>	November 1990	Oren et al.	424/468
<input type="checkbox"/>	<u>5178868</u>	January 1993	Malmqvist-Granlund et al.	424/490
<input type="checkbox"/>	<u>5229131</u>	July 1993	Amidon	424/451
<input type="checkbox"/>	<u>5358502</u>	October 1994	Herbig	604/892.1
<input type="checkbox"/>	<u>5445828</u>	August 1995	Pozzi	424/476
<input type="checkbox"/>	<u>5536507</u>	July 1996	Abramowitz	424/479
<input type="checkbox"/>	<u>5558879</u>	September 1996	Chen et al.	424/480
<input type="checkbox"/>	<u>5651985</u>	July 1997	Penners	424/469
<input type="checkbox"/>	<u>5656296</u>	August 1997	Khan et al.	424/473
<input type="checkbox"/>	<u>5736159</u>	April 1998	Chen et al.	424/480

ART-UNIT: 165

PRIMARY-EXAMINER: Page; Thurman K.

ASSISTANT-EXAMINER: Shelborne; Kathryne E.

ABSTRACT:

A composition that ensures selective release of an active ingredient at a given site, and in particular, a pharmaceutical composition enabling selective release of an active ingredient to be obtained at a target organ. The composition is intended for oral administration, providing selective release of its active ingredient in the colon.

22 Claims, 2 Drawing figures